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(54) **Catheter with enhanced ablation electrode**

(57) An ablation catheter comprises an elongated, flexible catheter body having proximal and distal ends and at least one lumen extending therethrough. A tip electrode having a length of at least about 3 mm is mounted on the distal end of the catheter body. The tip

electrode comprises a base material having an outer surface and a porous layer applied over at least a portion of the outer surface of the base material, the porous layer comprising metal nitride, metal oxide, metal carbide, metal carbonitride, carbon, carboxy nitride, or a combination thereof.

Description

FIELD OF THE INVENTION

[0001] The present invention is directed to a catheter having an enhanced ablation tip electrode.

BACKGROUND OF THE INVENTION

[0002] Electrode catheters have been in common use in medical practice for many years. They are used to stimulate and map electrical activity in the heart and to ablate sites of aberrant electrical activity.

[0003] In use, the electrode catheter is inserted into a major vein or artery, e.g., femoral artery, and then guided into the chamber of the heart which is of concern. Within the heart, the ability to control the exact position and orientation of the catheter tip is critical and largely determines how useful the catheter is.

[0004] A typical ablation procedure involves the insertion of a catheter having a tip electrode at its distal end into a heart chamber. A reference electrode is provided, generally taped to the skin of the patient. RF (radio frequency) current is applied to the tip electrode, and current flows through the media that surrounds it, i.e., blood and tissue, toward the reference electrode. The distribution of current depends on the amount of electrode surface in contact with the tissue as compared to blood, which has a higher conductivity than the tissue. Heating of the tissue occurs due to its electrical resistance. The tissue is heated sufficiently to cause cellular destruction in the cardiac tissue resulting in formation of a lesion within the cardiac tissue which is electrically non-conductive. During this process, heating of the electrode also occurs as a result of conduction from the heated tissue to the electrode itself. If the electrode temperature becomes sufficiently high, possibly above 60°C, a thin transparent coating of dehydrated blood protein can form on the surface of the electrode. If the temperature continues to rise, this dehydrated layer can become progressively thicker resulting in blood coagulation on the electrode surface. Because dehydrated biological material has a higher electrical resistance than endocardial tissue, impedance to the flow of electrical energy into the tissue also increases. If the impedance increases sufficiently, an impedance rise occurs and the catheter must be removed from the body and the tip electrode cleaned.

[0005] In clinical practice, it is desirable to reduce or eliminate impedance rises and, for certain cardiac arrhythmias, to create larger and/or deeper lesions. One method for accomplishing this is to monitor the temperature of the ablation electrode and to control the RF current delivered to the ablation electrode based on this temperature. If the temperature rises above a preselected value, the current is reduced until the temperature drops below this value. This method has reduced the number of impedance rises during cardiac ablations but

has not significantly increased lesion dimensions. The results are not significantly different because this method still relies on the cooling effect of the blood which is dependent on location in the heart and orientation of the catheter to endocardial surface.

[0006] Another method is to irrigate the ablation electrode, e.g., with physiologic saline at room temperature, to actively cool the ablation electrode instead of relying on the more passive physiological cooling of the blood. Because the strength of the RF current is no longer limited by the interface temperature, current can be increased. This results in lesions which tend to be larger and more spherical, usually measuring about 10 to 12mm. However, irrigated electrodes, which require a fluid delivery pump, are generally more expensive than standard ablation catheters. Additionally, the saline or other fluid used in the irrigated electrodes tends to accumulate in the patient.

[0007] Accordingly, a need exists for an improved approach for creating deeper ablation lesions.

SUMMARY OF THE INVENTION

[0008] The present invention is directed to a catheter having an enhanced tip electrode that permits the creation of deeper lesions. In one embodiment, the invention is directed to an ablation catheter comprising an elongated, flexible catheter body having proximal and distal ends and at least one lumen extending there-through. A tip electrode having a length of at least about 3 mm is mounted on the distal end of the catheter body. The tip electrode comprises a base material having an outer surface and a porous layer applied over at least a portion of the outer surface of the base material, the porous layer comprising metal nitride, metal oxide, metal carbide, metal carbonitride, carbon, carboxy nitride, or a combination thereof. Preferably a temperature sensor is mounted in the tip electrode.

[0009] In another embodiment, the invention is directed to an ablation system comprising a catheter and a source of radio frequency energy. The catheter comprises an elongated, flexible catheter body having proximal and distal ends and at least one lumen extending there-through. A tip electrode is mounted on the distal end of the catheter body. The tip electrode comprises a base material having an outer surface and a porous layer applied over at least a portion of the outer surface of the base material, the porous layer comprising metal nitride, metal oxide, metal carbide, metal carbonitride, carbon, carboxy nitride, or a combination thereof. The source of radio frequency energy is electrically connected to the tip electrode.

[0010] In another embodiment, the invention is directed to a method for ablating tissue in a patient. The method comprises providing a catheter as described above. The distal end of the catheter is introduced into the patient so that the tip electrode is in contact with the tissue to be ablated. Energy is applied to tip electrode, thereby

creating a lesion in the tissue.

DESCRIPTION OF THE DRAWINGS

[0011] These and other features and advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIG. 1 is a side view of an embodiment of the catheter of the invention.

FIG. 2 is a side cross-sectional view of a catheter body according to the invention, including the junction between the catheter body and tip section.

FIG. 3 is a side cross-sectional view of a catheter tip section in accordance with the invention.

FIG. 4 is a photograph showing a porous layer on a tip electrode.

FIG. 5 is a photograph showing a hydrogel layer applied on a porous layer on a tip electrode.

DETAILED DESCRIPTION

[0012] In a particularly preferred embodiment of the invention, there is provided a steerable catheter having a coated tip electrode. As shown in FIGs. 1 to 3, the catheter 10 comprises an elongated catheter body 12 having proximal and distal ends, a tip section 14 at the distal end of the catheter body 12, and a control handle 16 at the proximal end of the catheter body 12.

[0013] With reference to FIG. 2, the catheter body 12 comprises an elongated tubular construction having a single, axial or central lumen 18. The catheter body 12 is flexible, i.e., bendable, but substantially non-compressible along its length. The catheter body 12 can be of any suitable construction and made of any suitable material. A presently preferred construction comprises an outer wall 20 made of a polyurethane or PEBAX™. The outer wall 20 comprises an imbedded braided mesh of high-strength steel, stainless steel or the like to increase torsional stiffness of the catheter body 12 so that, when the control handle 16 is rotated, the tip section 14 of the catheter 10 will rotate in a corresponding manner. The outer diameter of the catheter body 12 is not critical, but is preferably no more than about 8 french, more preferably no more than about 7 french, still more preferably no more than about 6 french. Likewise the thickness of the outer wall 20 is not critical, but is thin enough so that the central lumen 18 can accommodate a puller wire, lead wire(s), and any other wires, cables or tubes. If desired, the inner surface of the outer wall 20 can be lined with a stiffening tube (not shown), as described in U.S. Patent No. 5,897,29, the entire disclosure of which is incorporated herein by reference.

[0014] As shown in FIGs. 2 and 3, the tip section 14 comprises a short section of tubing 22 having two lumens 24 and 26, although additional lumens can be pro-

vided if desired. The tubing 22 is made of a suitable non-toxic material that is preferably more flexible than the catheter body 12. A presently preferred material for the tubing 22 is braided polyurethane, i.e., polyurethane with an embedded mesh of braided high-strength steel, stainless steel or the like. The outer diameter of the tip section 14, like that of the catheter body 12, is preferably no greater than about 8 french, more preferably no more than about 7 french, still more preferably no more than about 6 french. The number and size of the lumens is not critical and depends on the specific application for which the catheter is to be used.

[0015] The useful length of the catheter, i.e., that portion that can be inserted into the body, can vary as desired. Preferably the useful length is at least about 100 cm, and more preferably ranges from about 110 cm to about 120 cm. The length of the tip section 14 is a relatively small portion of the useful length, and preferably ranges from about 3.5 cm to about 10 cm, more preferably from about 5 cm to about 6.5 cm.

[0016] A preferred means for attaching the catheter body 12 to the tip section 14 is illustrated in FIG. 2. The proximal end of the tip section 14 comprises an outer circumferential notch 28 that receives the inner surface of the outer wall 20 of the catheter body 12. The tip section 14 and catheter body 12 are attached by adhesive (e.g., polyurethane glue) or the like.

[0017] At the distal end of the tip section 14 is a tip electrode 30. The tip electrode 30 is attached to the tip section 14 with polyurethane glue or the like, or by any other suitable method known in the art. Preferably the tip electrode 30 has a diameter about the same as the outer diameter of the tubing 22 (e.g., less than or equal to 8 French, preferably less than or equal to 7 French). The tip electrode 30 has a length sufficient for ablating a lesion in heart tissue, preferably at least about 3 mm, more preferably from about 3 mm to about 6 mm, still more preferably from about 3.8 mm to about 4.5 mm.

[0018] The tip electrode 30 is made of a base material having an outer surface and comprising any suitable electrically-conductive material, such as platinum, gold, iridium, titanium, tantalum, stainless steel and alloys thereof. In a particularly preferred embodiment, the electrode comprises a platinum-iridium alloy (having 90% platinum by weight and 10% iridium by weight). Alternatively, the base material can comprise a non-metallic but electrically-conductive material, such as ceramic or electrically-conductive plastic. As would be recognized by one skilled in the art, other electrically-conductive materials can also be used for the tip electrode.

[0019] The tip electrode 30 is provided with a porous layer that has good electrical conductivity over at least a portion, and preferably over all, of the outer surface of the base material. If only a portion of the tip electrode is covered with the porous layer, the porous layer is preferably provided at the proximal end of the electrode to avoid edge effects, which can lead to coagulation at the joint of the tip electrode 30 and the tubing 22 of the tip

section 14.

[0020] The porous layer is made of metal nitride, metal oxide, metal carbide, metal carbonitride, carbon, carboxy nitride, or a combination thereof. The porous layer should also have good thermal conductivity, preferably equal to or exceeding that of platinum. The metal is preferably selected from titanium, iridium, platinum, vanadium, zirconium, niobium, ruthenium, molybdenum, hafnium, tantalum, cerium, chromium, yttrium, aluminum, nickel, and tungsten. Particularly preferred materials for the porous layer include titanium nitride, iridium oxide, and carbon. The porous layer preferably has a thickness ranging from about 0.1 micron to about 100 microns, more preferably from about 1 micron to about 50 microns, still more preferably from about 5 microns to about 30 microns.

[0021] The porous layer can be applied by any suitable technique, including, but not limited to, sputtering, ion implantation, ion plating, vacuum coating, and chemical vapor deposition. For example, a porous layer of titanium nitride can be applied by a reactive sputtering technique where the tip electrode base material is placed in a sputter chamber. Ion (such as argon) is accelerated toward a titanium target in the presence of nitrogen gas. The high speed impact of ion with the titanium target results in dislodging of atoms from the surface of the titanium target followed by reaction with nitrogen gas to form titanium nitride. During the coating process, the pressure of the nitrogen gas is reduced to create a porous structure.

[0022] The porous layer increases the surface area of the tip electrode by at least a factor of fifty. Preferably the surface area is increased 50 times to 5000 times, more preferably at least 500 times. FIG. 4 is a photograph showing an enlarged view of a porous layer in accordance with the invention, which demonstrates the resulting increased surface area. The porous layer of FIG. 4 comprises titanium nitride applied by a reactive sputtering technique, as described above.

[0023] The increased surface area of the tip electrode enhances the ability of the electrode to dissipate heat during ablation. As a result, a given amount of power (e.g., RF energy) can be applied to the tip electrode for a longer period of time than can be applied to a comparable tip electrode without the porous layer while still avoiding significant coagulation on the electrode. In fact, the cooling ability of a tip electrode having the porous layer and a length of about 4 mm is comparable to the cooling ability of an 8 mm tip electrode not having the porous layer. For most ablation procedures, a 4 mm electrode is preferred over an 8 mm electrode, assuming equivalent cooling ability, because multiple thermocouples are needed to accurately measure the temperature of an 8 mm tip electrode, whereas a single thermocouple is sufficient to accurately measure the temperature of a 4 mm tip electrode.

[0024] More specifically, for a standard ablation procedure, a temperature of about 60°C to about 65 °C is

sufficient to create the desired lesions. The temperature should be kept well below 100°C to avoid coagulation. At 50 W, typical power for an ablation procedure, the temperature of a tip electrode without a porous layer gets to 80°C very quickly, in about 30 seconds. In this time period, a lesion is created that is only about 6 to 7 mm deep. In contrast, a tip electrode having a porous layer at 50 W takes much longer, i.e., over a minute, to get to 80°C. As a result, the user has more time to ablate, resulting in the creation of deeper lesions, e.g. 8 to 10 mm deep, or deeper. In another preferred application, higher power can be applied to the tissue without raising the temperature above 80°C, thereby creating a deeper lesion.

[0025] In the embodiment shown, the tip section 14 further comprises a ring electrode 32 mounted on the tubing 22 proximal to the tip electrode 30. It is understood that the presence and number of ring electrodes 30 may vary as desired. The ring electrode 32 is slid over the tubing 22 and fixed in place by glue or the like. The ring electrode 32 can be made of any suitable material, and is preferably machined from platinum-iridium bar (90% platinum/10% iridium). If desired, the ring electrode 32 can also be covered, in whole or in part, with a porous layer as described above.

[0026] The tip electrode 30 and ring electrodes 32 are each connected to a separate lead wire 34. The lead wires 34 extend through the first lumen 24 of tip section 14, the central lumen 18 of the catheter body 12, and the control handle 16, and terminate at their proximal end in an input jack (not shown) that is connected to a source of RF energy and optionally plugged into an appropriate monitor (not shown). The portion of the lead wires 34 extending through the central lumen 18 of the catheter body 12, control handle 16 and proximal end of the tip section 14 may be enclosed within a protective sheath 36, which can be made of any suitable material, preferably polyimide. The protective sheath 36 is preferably anchored at its distal end to the proximal end of the tip section 14 by gluing it in the first lumen 24 with polyurethane glue or the like.

[0027] The lead wires 34 are attached to the tip electrode 30 and ring electrode 32 by any conventional technique. Connection of a lead wire 34 to the tip electrode 30 is accomplished, for example, by soldering the lead wire 34 into a first blind hole 38 in the tip electrode.

[0028] Connection of a lead wire 34 to the ring electrode 32 is preferably accomplished by first making a small hole through the tubing 22. Such a hole can be created, for example, by inserting a needle through the tubing 22 and heating the needle sufficiently to form a permanent hole. A lead wire 34 is then drawn through the hole by using a microhook or the like. The ends of the lead wire 34 are then stripped of any coating and soldered or welded to the underside of the ring electrode 32, which is then slid into position over the hole and fixed in place with polyurethane glue or the like.

[0029] One or more temperature sensing means (not

shown) are preferably provided for the tip electrode 30 and, if desired, the ring electrodes 32. In a particularly preferred embodiment, a single temperature sensing means is provided in the tip electrode. Any conventional temperature sensing means, e.g., a thermocouple or thermistor, may be used. A preferred temperature sensing means for the tip electrode 30 comprises a thermocouple formed by a wire pair. One wire of the wire pair is a copper wire, e.g., a number 40 copper wire. The other wire of the wire pair is a constantan wire, which gives support and strength to the wire pair. The wires of the wire pair are electrically isolated from each other except at their distal ends where they contact and are twisted together, covered with a short piece of plastic tubing, e.g., polyimide, and covered with epoxy. The plastic tubing is then attached by polyurethane glue or the like in the first blind hole 38 of the tip electrode along with the lead wire 34. The wires extend through the first lumen 24 in the tip section 14. Within the catheter body 12, the wires may extend through the protective sheath 36 with the lead wires 34. The wires then extend out through the control handle 16 and to a connector (not shown) connectable to a temperature monitor (not shown).

[0030] Alternatively, the temperature sensing means may be a thermistor. A suitable thermistor for use in the present invention is Model No. AB6N2-GC 14KA143E/37C sold by Thermometrics (New Jersey).

[0031] Additionally, a mechanism is provided for deflecting the tip section 14. The mechanism comprises a puller wire 50 extending through the catheter body 12. The puller wire 50 is anchored at its proximal end to the control handle 16 and at its distal end to the tip section 14. The puller wire 50 is made of any suitable metal, such as stainless steel or Nitinol, and is preferably coated with Teflon® or the like. The coating imparts lubricity to the puller wire 50. The puller wire 50 preferably has a diameter ranging from about 0.006 to about 0.010 inches.

[0032] A compression coil 52 is situated within the catheter body 12 in surrounding relation to the puller wire 50. The compression coil 52 extends from the proximal end of the catheter body 12 to the proximal end of the tip section 14. The compression coil 52 is made of any suitable metal, preferably stainless steel. The compression coil 52 is tightly wound on itself to provide flexibility, i.e., bending, but to resist compression. The inner diameter of the compression coil 52 is preferably slightly larger than the diameter of the puller wire 50. The Teflon® coating on the puller wire 50 allows it to slide freely within the compression coil 52. If desired, particularly if the lead wires 34 are not enclosed by a protective sheath 36, the outer surface of the compression coil 52 can be covered by a flexible, non-conductive sheath, e.g., made of polyimide tubing, to prevent contact between the compression coil 52 and any other wires within the catheter body 12.

[0033] The compression coil 52 is anchored at its proximal end to the proximal end of the catheter body

12 by proximal glue joint 51 and at its distal end to the tip section 14 by distal glue joint 53. Both glue joints 51 and 53 preferably comprise polyurethane glue or the like. The glue may be applied by means of a syringe or the like through a hole made between the outer surface of the catheter body 12 and the central lumen 18. Such a hole may be formed, for example, by a needle or the like that punctures the outer wall 20 of the catheter body 12 which is heated sufficiently to form a permanent hole.

The glue is then introduced through the hole to the outer surface of the compression coil 52 and wicks around the outer circumference to form a glue joint about the entire circumference of the compression coil 52.

[0034] The puller wire 50 extends into the second lumen 26 of the tip section 14. The puller wire 50 is anchored at its distal end to the tip electrode 30 within a second blind hole 40. A preferred method for anchoring the puller wire 50 within the tip electrode 30 is by crimping metal tubing 54 to the distal end of the puller wire 50 and soldering the metal tubing 54 inside the second blind hole 40. Anchoring the puller wire 50 within the tip electrode 30 provides additional support for the tip electrode on the flexible plastic tubing 22, reducing the likelihood that the tip electrode will separate from the tubing.

Alternatively, the puller wire 50 can be attached to the side of the tip section 14. Such a design is described in EP-A-0 904 796, the disclosure of which is incorporated herein by reference. Within the second lumen 26 of the tip section 14, the puller wire 50 extends through a plastic, preferably Teflon®, sheath 56, which prevents the puller wire 50 from cutting into the wall of the tubing 22 when the tip section is deflected.

[0035] Longitudinal movement of the puller wire 50 relative to the catheter body 12, which results in deflection of the tip section 14, is accomplished by suitable manipulation of the control handle 16. A suitable control handle design for use with the present invention is described in EP-A-0 928 601, the disclosure of which is incorporated herein by reference.

[0036] If desired, the catheter can be multidirectional, i.e., having two or more puller wires to enhance the ability to manipulate the tip section in more than one direction or to form two or more different curves. A description of such a design is provided in EP-A-0 904 796, EP-A-0 985 423, EP-A-0 982 047, EP-A-1 005 839 and EP-A-1 038 545, the disclosures of which are incorporated herein by reference.

[0037] If desired, a hydrogel layer can be applied over the porous layer on the tip electrode. The hydrogel layer can be made from a polymeric material or a protein. Preferred polymeric materials include polyglycolic acid, polylactic acid, copolymers of lactic/glycolic acids, polyesters, polyorthoesters, polyanhydrides, and polyaminoacids. Particularly preferred polymeric materials include polyvinylpyrrolidone and SLIP-COAT® (a hybrid polymer system based on polyvinylpyrrolidone and cellulose esters formulated in organic solvent solutions, commercially available from STS Biopolymers, Inc.,

Henrietta, New York). The polymeric material can be applied to the tip electrode to form the hydrogel layer by any suitable technique, such as by a dip process or a spray process, followed by drying at 40° to 100°C. Preferred proteins include albumin, collagen and gelatin.

[0038] FIG. 5 is a photograph showing an enlarged view of a hydrogel layer applied over a porous layer in accordance with the invention. The porous layer comprises 4 titanium nitride applied by a reactive sputtering technique, as described above. The hydrogel layer comprises polyvinylpyrrolidone dip-coated onto the electrode and UV-cured.

[0039] The hydrogel layer creates a more lubricous surface on the tip electrode, allowing the electrode to be maneuvered more easily and safely into position with less patient trauma. Additionally, the hydrogel layer creates a surface on the tip electrode to which coagulate will not stick, which is particularly beneficial for ablation procedures.

[0040] Additionally, the hydrogel layer can be combined with drugs or other therapeutic agents to allow delivery of the drugs or agents by diffusion, co-dissolution and/or resorption. Suitable agents for impregnation into the hydrogel layer include, for example, anti-inflammatory agents, antithrombogenic agents, antibiotics, and antimicrobials. Examples of suitable coating materials incorporating are those sold under the name STS HEPARIN (such as heparin-benzalkonium chloride in isopropanol and heparin-tridodecylmethylammonium chloride in other solvents, commercially available from STS Biopolymers, Inc.).

[0041] The preceding description has been presented with reference to presently preferred embodiments of the invention. Workers skilled in the art and technology to which this invention pertains will appreciate that alterations and changes in the described structure may be practiced without meaningfully departing from the principal, spirit and scope of this invention.

[0042] Accordingly, the foregoing description should not be read as pertaining only to the precise structures described and illustrated in the accompanying drawings, but rather should be read consistent with and as support to the following claims which are to have their fullest and fair scope.

the porous layer comprising metal nitride, metal oxide, metal carbide, metal carbonitride, carbon, carboxy nitride or a combination thereof.

- 5 2. A catheter according to claim 1, wherein the tip electrode has a length of at least about 3 mm and preferably has a length ranging from 3 mm to 6 mm, more preferably from 3.8 mm to 4.5 mm.
- 10 3. A catheter according to claim 1 or claim 2, wherein the porous layer comprises metal nitride, metal oxide, metal carbide or metal carbonitride, wherein the metal is titanium, iridium, platinum, vanadium, zirconium, niobium, ruthenium, molybdenum, hafnium, tantalum, cerium, chromium, yttrium, aluminum, nickel or tungsten.
- 15 4. A catheter according to claim 3, wherein the porous layer comprises titanium nitride or iridium oxide.
- 20 5. A catheter according to any one of claims 1 to 4, wherein the porous layer covers all of the outer surface of the base material.
- 25 6. A catheter according to any one of claims 1 to 5, wherein the porous layer has a thickness ranging from 1 micron to 50 microns.
- 30 7. A catheter according to any one of claims 1 to 6, further comprising a temperature sensor mounted in the tip electrode.
- 35 8. A catheter according to any one of claims 1 to 7 having a useful length of at least 100 cm.
- 40 9. An ablation system comprising: a catheter as defined in any one of claims 1 to 8 and a source of radio frequency energy electrically connected to the tip electrode.
- 45 10. An ablation system according to claim 10, for use in ablating tissue in a patient.

Claims

1. An ablation catheter comprising:

an elongated, flexible catheter body having proximal and distal ends and at least one lumen extending therethrough; and
a tip electrode mounted on the distal end of the catheter body, wherein the tip electrode comprises a base material having an outer surface and a porous layer applied over at least a portion of the outer surface of the base material,

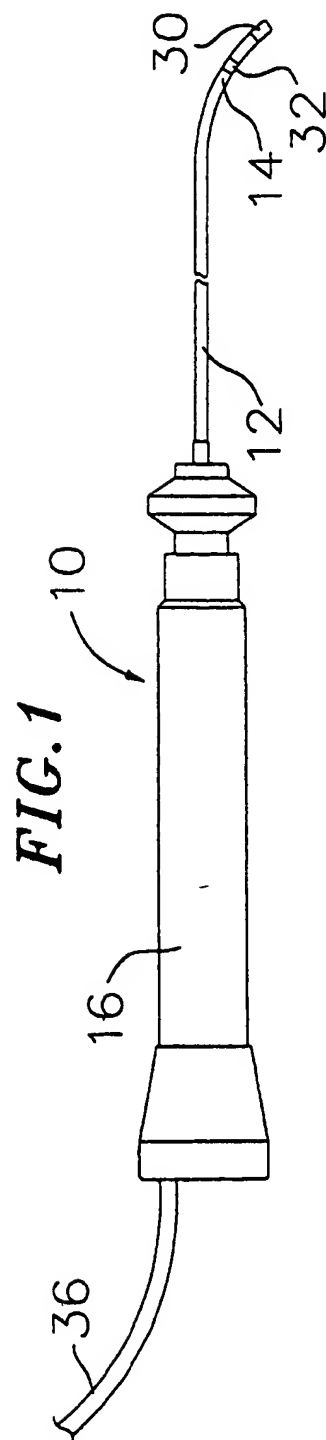


FIG. 2

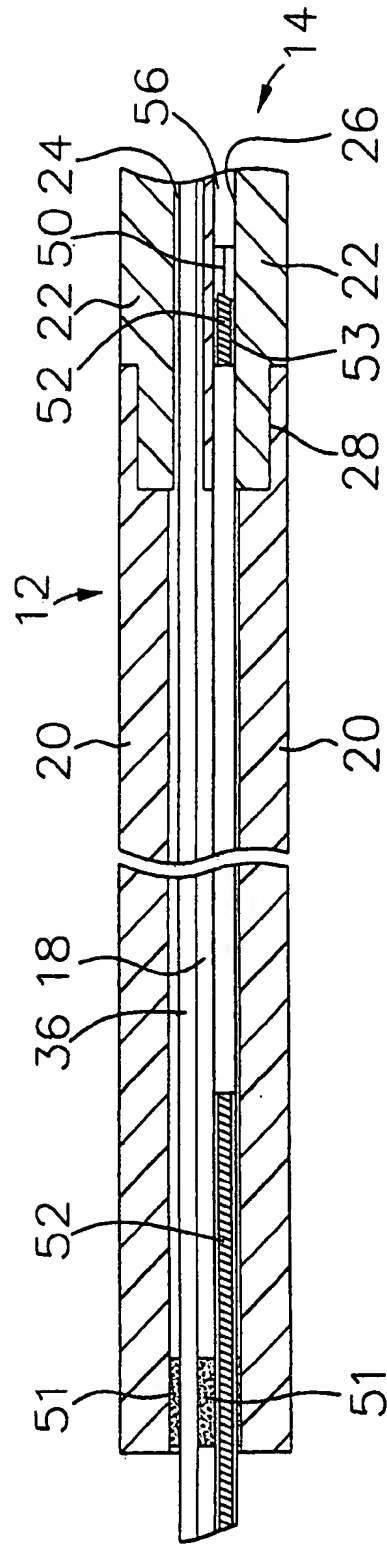


FIG. 3

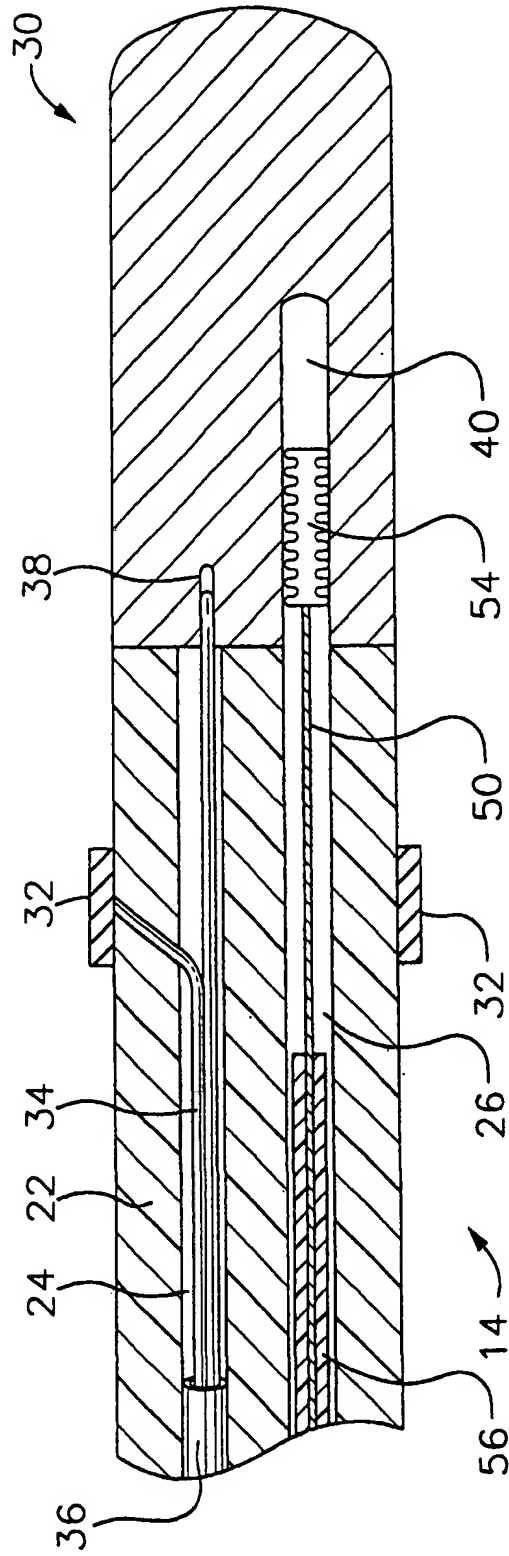


Fig. 1

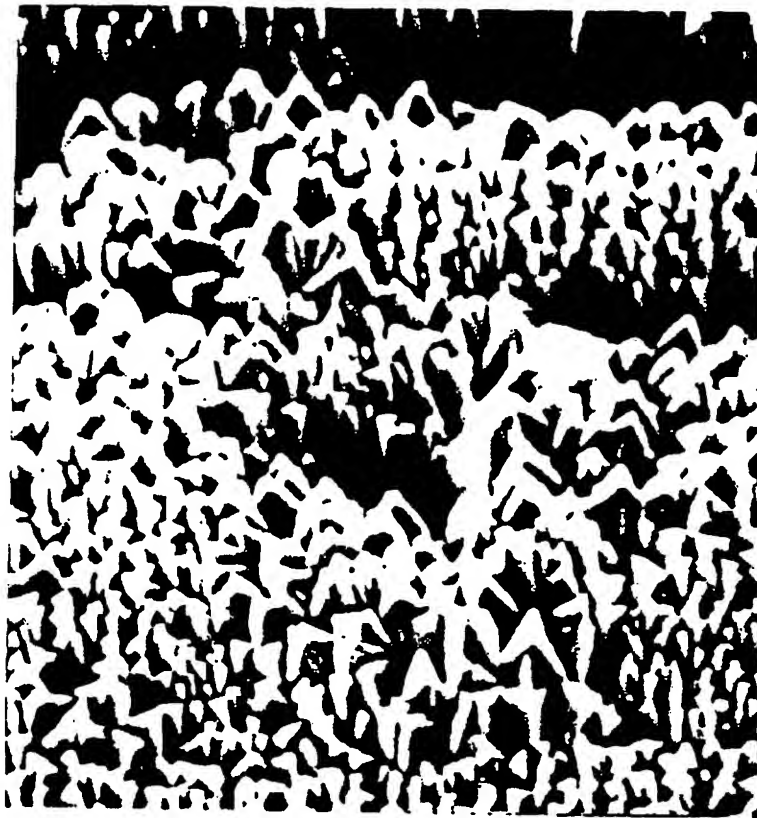


Fig. 5





European Patent
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EUROPEAN SEARCH REPORT

Application Number
EP 01 30 3971

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Incl. Cl. 7)
A	US 4 440 178 A (BUSSARD ADRIEN ET AL) 3 April 1984 (1984-04-03) * the whole document *	1	A61B18/14
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			A61B A61N H01L
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 9 July 2001	Examiner Papone, F
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**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 01 30 3971

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09-07-2001

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